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Remarks

Rejections

35 U.S.C. §102(b)

Claims 1-18 and 31-38 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,254,634 to Anderson et al. The Office Action asserts that regarding claims 1, 15 and 31, Anderson et al. disclose in the Abstract preparing a mixture of a hydrophilic fluorescing agent and hydrophobic lubricant (col. 8, lines 58-67 and col. 9) and applying the mixture to the surface of a medical device (col. 4, lines 7-17) to form a coating capable of exhibiting fluorescence (col. 4, lines 7-17).

Claim 1 has been amended to incorporate the limitations found in claim 2. Applicants submit that claim 1 is not anticipated by Anderson et al. Claim 1 is directed to a mixture of a lubricant and a fluorescing agent, such combination being employed for detecting the location and/or uniformity of the lubricious coating

Anderson et al., US 6,254,634

Anderson et al. describes an article (e.g. in the form of an implantable medical device) in the form of a support material bearing an *intermediate layer* consisting of a functional silicone polymer formulation, the intermediate layer having *photoimmobilized* thereon a *target compound*.

Photoimmobilization, it is described, can be accomplished by the activation of one or more photoreactive groups. In one embodiment, the target compound is itself derivatized with one or more photoreactive groups. In an alternative embodiment, the target compound is attached to the intermediate layer via a coupling compound, wherein the coupling compound provides at least one photoreactive group for photoimmobilizing the coupling compound to the intermediate layer, and either a photoreactive or thermoreactive group for a photochemical or thermochemical reaction between the coupling compound and target compound. Alternatively, the coupling compound provides a thermochemical group for thermochemically covalently attaching the coupling compound to the intermediate layer, and a photoreactive group for photoimmobilizing the coupling compound to the target compound. In another alternative embodiment, the intermediate layer itself provides one or more photoreactive groups for

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attachment of the target compound (col. 3, lines 22-40).

The target compound can include one or more latent reactive groups that *respond to specific applied external stimuli to undergo active specie generation with resultant covalent bonding to an adjacent support*. Latent reactive groups include groups of atoms in a molecule which retain their covalent bonds unchanged under conditions of storage but which, upon activation, form covalent bonds with other molecules (col. 4, lines 31-38).

Intermediate layers are preferably capable of being applied to a support material and *covalently attached* to a target compound (e.g. by the activation of photoreactive groups), in order to provide a durable and tenacious coating (col. 5, lines 22-25). The only examples provided for the intermediate layer include functional silicone formulations.

The paragraph at col. 8, lines 58-67, Anderson et al. discuss target molecules:

Suitable target molecules for use in the present invention encompass a diverse group of substances and can be immobilized singly or in combinations with other types of target molecules. Typically, target molecules are selected so as to confer one or more particular desired properties to the surface and/or to the device or article incorporating or bearing the surface.

Anderson et al. go on to provide examples of target compounds in the table at column 9. This list includes synthetic polymers including those listed as having a functional activity of lubricity, carbohydrates, proteins, lipids, nucleic acid, drugs/vitamins/cofactors, non-polymeric materials including dyes and fluorescent compounds.

However, contrary to the statement made in the final paragraph on page 2 of the Office Action, Anderson et al. do not disclose observing fluorescent emission to determine the location and uniformity of the lubricant. Anderson et al. in fact make no specific suggestion or teaching to combine any lubricant with any fluorescing agent so as to provide a method of visualizing the lubricant to determine location and/or uniformity of the lubricant. Consequently, Applicants submit that Anderson et al. did not contemplate the use of a fluorescing agent to detect the presence and/or uniformity of the lubricant. Applicants thus submit that using the fluorescing agent for the specific purpose of where and/or how much lubricant exists in various places on a medical device is not taught by Anderson et al.

While there is a general teaching that lubricants, fluorescing agents, among many

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other types of compounds, may be reacted onto the intermediate layer of an article, the list provided by Anderson et al. is long, and there is no specific teaching to combine a fluorescing agent with a lubricant. Therefore, Applicants submit that claim 1 is not anticipated by Anderson et al. Claim 2 has been canceled. Furthermore, as claims 3-14 depend from claim 1 and further limit claim 1, they also are not anticipated by Anderson et al. at least for the reasons that claim 1 is not anticipated by Anderson et al.

Applicants traverse the rejection with respect to claims 15 and 38. Claims 15 and 38 of the present application are directed to a *fluorescented* lubricant which has groups on the lubricant molecule itself which will fluoresce. Anderson et al. do not describe or claim any lubricant which incorporates fluorescent groups on the lubricant molecule itself. There is no suggestion by Anderson et al. that the lubricants disclosed in the table at col. 9 also provide fluorescence. Thus, the invention of claims 15 and 38 are not anticipated by Anderson et al. Applicants respectfully request withdrawal of the rejection of claims 15 and 38 under 35 U.S.C. §102(b) as anticipated by Anderson et al.

Claim 16 as amended is directed to a coating for a medical device which is a mixture of a hydrophobic lubricant, a hydrophilic fluorescing agent and a surfactant. Anderson et al. does not suggest surfactants for use in combination with a hydrophobic lubricant and a hydrophilic surfactant. Again, while Anderson et al. describes a long list of target compounds, this specific combination is not suggested. Therefore, claim 16 is not anticipated by Anderson et al. Claims 17 and 18 depend from claim 16 and are not anticipated by Anderson et al. for at least the reasons that claim 16 is not anticipated by Anderson et al.

Claim 31, as amended, is directed to a medical device comprising a *single coating comprising a mixture* of at least one lubricant and at least one fluorescing agent.

Anderson et al. describes an intermediate layer to which is photoimmobilized a target compound. The intermediate layer is applied prior to the application of the target compound. The target compound is then applied and reacted with the intermediate layer such that covalent bonding occurs. The invention of claim 31, in contrast, is directed to an embodiment wherein there is no intermediate layer, but rather a single coating of a lubricant and a fluorescing agent. Because there is no covalent bonding of the lubricant or fluorescing agent as claimed in 31, a chemically different composition is found on the surface of the device according

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to claim 31 than combination of an intermediate layer and target compound as described and claimed by Anderson et al.

Therefore, claim 31 is not anticipated by Anderson et al. Claims 32-37 depend from claim 31 and are not anticipated by Anderson et al. at least for the reasons that claim 31 is not anticipated.

Further with respect to claim 32, as discussed above, Anderson et al. does not describe a mixture of a hydrophobic lubricant, a hydrophilic fluorescing agent and a *surfactant*. Anderson et al. makes no reference whatsoever to the use of any surfactants. Therefore, Anderson lacks an element necessary to support a rejection of claim 32 under 35 U.S.C. §102(b). Consequently, claim 32 is not anticipated by Anderson et al.

Based on the foregoing amendments and arguments, Applicants respectfully request withdrawal of the rejection of claims 1-18 and 31-38 under 35 U.S.C. §102(b) as anticipated by Anderson et al.

The term "hydrophobic" as it refers to the lubricant and "hydrophilic" as it refers to the fluorescing agent, have been removed from independent claims 1 and 31 because these terms are viewed as being unnecessary to the patentability of the claims.

35 U.S.C. §103(a)

Claims 19-30 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,254,634 B1 to Anderson et al.

The Office Action asserts that regarding claims 19-23, Anderson et al. disclose a lubricious coating comprising a fluorescent dye (Abstract; col. 8, lines 58-67; col. 9) and a method for determining the presence of a lubricious coating.

Applicants traverse the rejection.

Claim 19 depends from claim 16 which has been amended. Claim 16 is directed to a medical device comprising a coating which includes a surfactant in combination with a hydrophobic lubricant and a hydrophilic fluorescing agent. Anderson et al. does not suggest the combination of a hydrophobic lubricant and a hydrophilic fluorescing agent, and makes no mention of the use of surfactants at all. Therefore, Anderson et al. is lacking an element and claim 16 is therefore not obvious over Anderson et al. Claim 19 is not obvious over Anderson et

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al. for at least the reasons that claim 16 is not obvious over Anderson et al.

Applicants respectfully request withdrawal of the rejection of claim 19 under 35 U.S.C. §103(a) as obvious over Anderson et al.

Claims 20-30 are directed to applying a lubricious coating which includes a fluorescing agent on the *inner* surface of a stent *retaining sleeve*. It is difficult to ensure that lubricant has been adequately applied to such a surface. Thus the present invention includes a fluorescing agent in the lubricant such that the lubricant can be visualized and it can be determined whether sufficient coating is present or not. The presence of and uniformity of a lubricious coating facilitates the smooth and efficient release of a stent from the *retaining sleeve*. Nowhere is it suggested in Anderson et al. to employ a mixture of a lubricant and a fluorescing agent to the inner surface of a stent retaining sleeve. Thus, Anderson et al. lacks the elements necessary to support an obviousness rejection because Anderson et al. makes no suggestion to apply the mixture to such an inner surface.

Further with respect to claims 21-30, Anderson et al. make no specific suggestion to using a fluorescing agent in a lubricant such that the lubricant may be observed.

Therefore, Applicants respectfully request withdrawal of the rejection of claims 20-30 under 35 U.S.C. §103(a) as obvious over Anderson et al.

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CONCLUSION

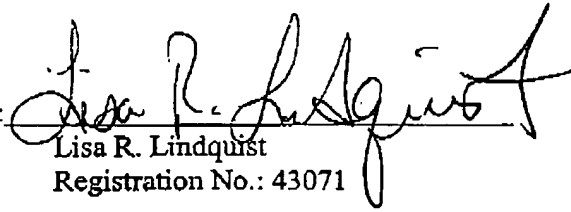
Claims 1 and 3-38 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing amendments and arguments, Applicants respectfully request reconsideration and an early allowance of the claims as presented.

Respectfully submitted,

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Marked-Up Text

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1. (Amended) A method for detecting the presence and uniformity of a lubricious coating on a medical device comprising the steps of:

- a) preparing a mixture of [a biocompatible] at least one [hydrophilic] fluorescing agent and at least one [hydrophobic] lubricant;
- b) applying said mixture to the surface of a medical device to form a coating capable of exhibiting fluorescence; and
- c) subjecting the surface of the medical device to a source of energy capable of inducing a fluorescent emission; and
- d) observing the fluorescent emission to determine the location, uniformity or both of said lubricant.

16. (Amended) A [medical device comprising] a lubricious coating for use on a medical device, said coating comprising a mixture of at least one hydrophobic lubricant, [and a] at least one hydrophilic fluorescent dye and at least one surfactant, said coating fluorescing upon exposure to an energy source capable of inducing fluorescence.

31. (Amended) A [lubricious coating for use on a] medical device comprising a single coating, said coating comprising a mixture of:

- a) at least one [hydrophobic] lubricious compound; and
- b) at least one [hydrophilic] fluorescing agent.

32. (Amended) The [coating] medical device of Claim 31 further comprising at least one surfactant.

33. (Amended) The [coating] medical device of Claim 32 [31 prepared by mixing] wherein said lubricious compound is hydrophobic [lubricious compound] and said [hydrophilic] fluorescing agent is hydrophilic [in a cosolvent blend].

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34. (Amended) The [coating] medical device of Claim 31 wherein said lubricious compound is silicone based.

35. (Amended) The [coating] medical device of Claim 31 wherein said lubricious compound is polydimethylsiloxane.

36. (Amended) The [coating] medical device of Claim 31 wherein said at least one fluorescing agent is a fluorescein, rhodamine, triarylmethane, derivative thereof or mixture thereof.

37. (Amended) The [coating] medical device of Claim 36 wherein said at least one fluorescing agent is 5-carboxyfluorescein, 6-carboxyfluorescein, indocyanine green, lissamine green, rose bengal, or mixture thereof.